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**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION**

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| <p>MARK L. SHURTLEFF, ATTORNEY GENERAL OF THE STATE OF UTAH, <i>ex rel.</i> THE STATE OF UTAH,</p> <p style="text-align: center;">Plaintiff,</p> <p>v.</p> <p>JANSSEN ORTHO LLC, ORTHO-MCNEIL- JANSSEN PHARMACEUTICALS, INC., and ASTRAZENECA PHARMACEUTICALS LP,</p> <p style="text-align: center;">Defendants.</p> | <p>Case No. 2:10-CV-00519-BSJ</p> <p style="text-align: center;">PLAINTIFF’S MOTION TO REMAND FOR LACK OF SUBJECT MATTER JURISDICTION</p> |
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Plaintiff, the Attorney General of the State of Utah, on behalf of the State, respectfully submits this Motion to Remand for Lack of Subject Matter Jurisdiction. In support, Plaintiff would show the Court as follows:

I. INTRODUCTION

On May 3, 2010, Plaintiff filed this action in the Third Judicial District Court of Salt Lake County, West Jordan Department, against Janssen Ortho LLC, Ortho-McNeil-Janssen Pharmaceuticals Inc. (collectively “Janssen”) and AstraZeneca Pharmaceuticals LP (“AstraZeneca”) (collectively “Defendants”). On May 19, 2010, Plaintiff filed its Amended Complaint. Therein, Plaintiff asserts claims based *exclusively* on Utah statutory and common law, including violations of the Utah False Claims Act (UTAH CODE ANN. §§ 26-20-4, 26-20-7) and the Utah Pattern of Unlawful Activity Act (UTAH CODE ANN. §§ 76-10-1601, *et seq.*), as well as claims of strict products liability, fraud, negligent misrepresentation, and negligence.

Plaintiff’s claims arise out of Defendants’ many-year campaign to promote their pharmaceutical products, Risperdal and Seroquel, respectively, in ways that were false,

misleading and illegal under Utah *state* law. Though both drugs are approved by the federal Food and Drug Administration for a limited number of diagnosed medical conditions, Defendants violated Utah state law by falsely and illegally marketing these drugs for non-indicated uses. Defendants knew their drugs had potentially dangerous medical side effects and were hazardous for use in many patients, but Defendants failed to provide any such warnings, again in violation of Utah state law.

Despite the fact that Plaintiff's Amended Complaint asserts claims based *solely* on Utah statutory and common law, Defendants removed this case to federal court. In support of removal, Defendants argue that Plaintiff's Amended Complaint raises substantial and disputed issues of federal law that require the construction and application of the federal Medicaid statute. Specifically, Defendants contend Plaintiff's Amended Complaint raises federal questions regarding:

1. the State's obligation under the Federal Medicaid statute to reimburse Medicaid participants for prescriptions for FDA-approved atypical antipsychotics; and
2. the meaning of the term "medically accepted" as used in the Federal Medicaid statute.

These arguments, however, are nothing more than an effort to manufacture a basis for removal when, in fact, no such basis exists. Indeed, Defendants attempt to re-plead Plaintiff's claims as something different than those actually pled. Unfortunately for Defendants, as detailed below, they are obligated to accept Plaintiff's state law causes of actions as pled, without alteration and cannot re-plead Plaintiff's claims in a manner that best suits their needs for the creation of federal question jurisdiction.

Defendants' tactics are neither surprising nor novel. These shop-worn arguments have been repeatedly advanced by pharmaceutical manufacturers, including Defendants, and every

federal court that has addressed such arguments, save one, has routinely rejected them and ordered remand to state court.

II. ARGUMENT & AUTHORITIES

Defendants have failed to meet their heavy burden to establish federal subject matter jurisdiction. For the reasons set forth below, the State of Utah respectfully requests that this action be remanded to the Third Judicial District Court of Salt Lake County, West Jordan Department, Utah.

A. **Removal Jurisdiction Must Be Strictly Construed.**

The United States Supreme Court has consistently held that the district courts of the United States are “courts of limited jurisdiction. They possess only that power authorized by Constitution and statute.” *Exxon Mobil Corp. v. Allapattah Serv’s*, 545 U.S. 546, 552 (2005) (quoting *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994)). This rule embodies the “due regard for the rightful independence of state governments, which should actuate federal courts, [by requiring] that they scrupulously confine their own jurisdiction to the precise limits which the statute has defined.” *Beneficial Nat’l Bank v. Anderson*, 539 U.S. 1, 18 (2003) (Scalia, J. dissenting) (quoting *Healy v. Ratta*, 292 U.S. 263, 270 (1934)). Courts are obliged to strictly construe removal jurisdiction. *See Shamrock Oil & Gas Corp. v. Sheets*, 313 U.S. 100, 108-109 (1941).

It is well-settled in the Tenth Circuit that removal statutes are to be narrowly and strictly construed and all doubts and uncertainties resolved in favor of remand. *Fajen v. Found. Reserve Ins. Co.*, 683, F.2d 331, 333 (10th Cir. 1982); *see also Lichfield v. Int’l Survivors Action Comm.*, No. 2:05-CV-254, 2005 U.S. Dist. LEXIS 45301, *2-3 (D. Utah June 22, 2005). Indeed, “in the case of removal, there is a presumption against federal jurisdiction.” *Martin v. Franklin Capital Corp.*, 251 F.3d 1284, 1290 (10th Cir. 2001). The burden of establishing federal jurisdiction

falls to the party invoking the removal statute. *Montoya v. Chao*, 296 F.3d 952, 955 (10th Cir. 2002); *Utah v. Eli Lilly & Co.*, 509 F. Supp. 2d 1016, 1020 (D. Utah 2007).

B. Utah’s “Well-Pleaded” Claims Do Not “Arise Under” Federal Law.

District courts have original subject-matter jurisdiction over “all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. Under the general federal removal statute, 28 U.S.C. section 1441(a), a defendant may only remove a “civil action brought in a State court of which the district courts of the United States have original jurisdiction.” Absent diversity jurisdiction, a civil action filed in state court may only be removed if the claim “arises under” federal law. *Beneficial Nat’l Bank*, 539 U.S. at 6 (citing 28 U.S.C. § 1441(b)); *Felix v. Lucent Techs., Inc.*, 387 F.3d 1146, 1154 (10th Cir. 2004). If a case is improperly removed, the federal court must remand the action because it has no subject-matter jurisdiction to decide the case. *RMP Consulting Group, Inc. v. Datronic Rental Corp.*, No. 98-5062, 1999 U.S. App. LEXIS 19246, *10 (10th Cir. Aug. 16, 1999).

The statutory requirement that there be original jurisdiction means that a question of federal law “must be disclosed upon the face of the complaint, unaided by the answer or by the petition for removal.” *Gully v. First Nat’l Bank*, 299 U.S. 109, 113 (1936). Whether the claim arises under federal law must be determined by applying the “well-pleaded complaint rule, which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff’s properly pleaded complaint.” *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987). That a federal question may arise in connection with a defense or counterclaim is not enough. *State v. W. Estate Servs. Inc.*, 139 Fed. Appx. 37, 38 (10th Cir. 2005). The plaintiff’s statement of the cause of action must affirmatively show it is based on federal law. *Beneficial Nat’l Bank*, 539 U.S. at 6-8. As the Supreme Court expressly stated in *Caterpillar*,

“[t]he (well pleaded complaint) rule makes the plaintiff the *master of the claim*; he or she may *avoid* federal jurisdiction by exclusive reliance on state law. 482 U.S. at 392 (emphasis added).

Throughout its Amended Complaint, Utah is clear that its claims are based entirely on Utah law. *See, e.g.*, Amended Compl. at ¶¶ 1, 17, 22, 132, 138, 145, 152, 156, 159, 160. It is also clear that any reference to federal law is made *only* as such federal law applies to and has been adopted by Utah law. *See, e.g.*, Amended Compl. at ¶ 25 (stating that the “Utah Medicaid program restricts its coverage of drugs to only the medically accepted indications that are FDA-approved or supported by an officially recognized compendia”)

Therefore, because Utah exclusively relied on Utah statutory and common law causes of action, application of the well-pleaded complaint rule requires that it be permitted to pursue its claims in Utah state court.

C. Utah’s Complaint Does Not Raise a “Substantial Federal Question.”

A narrow exception to the “well-pleaded complaint” rule provides federal jurisdiction in limited circumstances where the plaintiff’s claims raise a “substantial federal question.” *Franchise Tax Bd. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1 (1983). Under the substantial federal question doctrine, a state law cause of action arises under federal law where “it appears that some substantial, disputed question of federal law is a *necessary* element of one of the well-pleaded claims.” *Id.* at 13 (emphasis added). The underlying disputed federal issue must be sufficiently “substantial” such that there is a clear indication of a “serious federal interest in claiming the advantages thought to be inherent in a federal forum.” *Grable*, 545 U.S. at 312.

1. Utah's Claims Do Not Raise Substantial or Disputed Issues of Federal Law.

Defendants suggest that a federal question is raised by Utah's complaint because the complaint allegedly depends on the relevance of the definition of the term "medically accepted" found in the federal Medicaid statute but, this not the case when, as here, the complaint does not invoke federal law.

The application of the substantial federal question doctrine is explained by the Supreme Court in *Grable*. In *Grable*, the IRS had seized the plaintiff's property to satisfy a federal tax delinquency. 545 U.S. at 310. After notifying the plaintiff by certified mail of the pending sale of its property, the IRS sold the property, conveying a quitclaim deed to the defendant. *Id.* at 310-311. The plaintiff subsequently brought a quiet title action against the defendant in state court alleging the IRS' notice of the sale was deficient, because, plaintiff claimed, federal law required personal service of the notice. *Id.* at 311. The defendant removed the case, asserting the interpretation of the federal tax code's notice provision was a substantial federal question conferring "arising under" jurisdiction in federal court. *Id.* The Supreme Court agreed, but refused to adopt a bright line rule for jurisdiction in such cases, opting instead to analyze cases in light of the following question:

Does a state-law claim necessarily raise a stated federal issue, *actually disputed and substantial*, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities?

Id. at 314 (emphasis added).

Because an essential element of the plaintiff's claim in *Grable* was that the IRS failed to follow federal tax law governing the notice of the tax sale, on its face the claim stood or fell on a dispute regarding the interpretation and application of federal tax law. Thus, the Court found the case "arose under" federal law. *Id.* at 315. However, as the Court more recently held in *Empire*

Healthchoice Assurance Inc., v. McVeigh, 547 U.S. 677 (2006), the type of federal jurisdiction allowed under *Grable* is a “slim category.” *Id.* at 701. Further, where a complaint seeking the recovery of Medicaid funds “sets forth exclusively state law causes of action, there is no question of federal law, substantial or otherwise to be determined.” *Commonwealth v. TAP Pharm. Products, Inc.*, 415 F. Supp. 2d 516, 524 (E.D. Pa. 2005); *Commonwealth v. Philip Morris, Inc.*, 942 F. Supp. 690, 694 (D. Mass. 1996) (“*Philip Morris*”). The fact that a federally created program serves as the initial source of funds the State seeks to recover does not necessitate any construction of federal law. *Commonwealth v. Eli Lilly & Co.*, 511 F. Supp. 2d 576, 585 (E.D. Pa. 2007); *Gingerich v. White Pigeon Cmty. Sch.*, 736 F. Supp. 147 (W.D. Mich. 1990) (finding the receipt and use of federal funds insufficient to confer federal jurisdiction).

Here, Defendants’ removal fails to satisfy the *Grable* test because Utah’s state law claims do not involve a substantial, disputed question of federal law that is a necessary element of the State’s claims. Under the federal Medicaid statute, “[a] State may exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication.” 42 U.S.C. § 1396r-8(d)(1)(B)(i). “The term ‘medically accepted indication’ means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act . . . or the use of which is supported by one or more citations included or approved for inclusion in any of the [approved] compendia.” 42 U.S.C. § 1396r-8(k)(6). According to Defendants, “at the core of this case” is whether Utah reimbursed Medicaid recipients for non-medically accepted indications. Defendants are wrong. In fact, because Plaintiff has not alleged Defendants violated federal law, whether reimbursement was afforded for non-medically accepted indications is irrelevant.

[W]hile the prescription of the drugs for such “off-label” uses was the alleged goal—and the alleged harm—the submission of claims for non-medically necessary uses was not in and of itself the tortious conduct. In other words, the central dispute in this case . . . will be factual. Here, the central question is whether the Defendants’ advertising and promotion methods violate [Utah] tort law, not what is or is not a medically accepted indication or medically necessary use.

State ex rel. McMaster v. Eli Lilly & Co., No. 7:07-cv-1875-HMH, 2007 U.S. Dist LEXIS 56847 (D.S.C. Aug 3, 2007); *State ex rel. McMaster v. Janssen Pharmaceutica, Inc.*, No. 7:07-cv-1452-HMH, 2007 U.S. Dist. LEXIS 49904 (D.S.C. July 10, 2007); *Commonwealth v. Eli Lilly & Co.*, 511 F. Supp. 2d 576, 581 (E.D. Pa. 2007). Because the State’s causes of action, all clearly sounding in Utah statutory or common law, do not allege that Defendants violated any federal statute or regulation, it is axiomatic that proof of these violations of Utah law *cannot* turn on the interpretation of the term “medically accepted” found in the federal Medicaid statute. Thus, the Court need not “ascribe any meaning to the words ‘[medically accepted]’ for the [State] to prevail. Instead, the [State] must prove the Defendants’ conduct was in derogation of state law.” *Commonwealth v. TAP Pharmaceutical Prods. Inc.*, 415 F. Supp. 516, 525-26 (E.D. Pa. 2005).

Because none of Plaintiff’s causes of action require an interpretation of the term “medically accepted” in order to adjudicate Plaintiff’s state law claims—this term cannot be found in any of the Utah statutes alleged to have been violated and is not a recognized element of the common law causes of action asserted—there is no *actual dispute* regarding the meaning of “medically accepted.” *Grable*, 545 U.S. at 315.

Furthermore, even assuming *arguendo* that the meaning of “medically accepted” was in fact an issue in Plaintiff’s case, “the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction.” *Merrell Dow Pharm. v. Thompson*, 478 U.S. 804, 813 (1986). *Merrell Dow* was a pharmaceutical product liability case initially

filed in state court based on state tort law, including negligence, strict liability and breach of warranty. *Id.* 805. The plaintiffs alleged that defendant's drug was misbranded in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") in that the drug's labeling did not provide adequate warning regarding the dangers associated with its use and that violation of the federal statute proximately caused their injuries. *Id.* at 806. In order for the plaintiffs to prevail they would have had to demonstrate a violation of the federal labeling standard. *Id.* at 805-06. The district court nonetheless found that federal question jurisdiction did not exist. *Id.* at 817.¹ In light of plaintiffs' allegations, defendant removed the case to federal court arguing the action was based, in part, on an alleged claim arising under the laws of the United States. *Id.* The Supreme Court affirmed remand. *Id.* at 817.

In so holding, the Supreme Court rejected defendant's assertion that because violation of federal labeling law was invoked as a basis for the state tort claims, the claims must therefore "arise under" federal law. The Court found instead that because federal labeling law did not *create* the cause of action, plaintiff's claims did not arise under federal law. *Id.* at 809. The Court held that for removal to be proper, "some substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims." 478 U.S. at 813. In this case, the State of Utah is not even alleging that Defendants violated the federal Medicaid law, so the relation of federal law to the State's claims is more tenuous.

Next, Defendants' assertion that Plaintiff's claims are dependent upon a judicial construction of the term "medically accepted" is misplaced. In fact, even if Plaintiff were to

¹ Taking Defendants' argument even one step further, the allegation of a violation of a federal statute as a basis for a negligence *per se* cause of action is not sufficient to confer federal question jurisdiction. *Mulcahey v. Columbia Organic Chem. Co.*, 29 F.3d 148, 153 (4th Cir. 1994) (alleging violations of CERCLA as a basis for claims of negligence *per se*); *Polcha v. AT&T Nassau Metals Corp.*, 837 F. Supp. 94, 96 (M.D. Pa. 1993) (same).

prove at trial that Defendants violated the federal Medicaid law, “it would not necessarily follow that they committed Medicaid fraud as defined [under Utah state law].” *State v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, No. 1:08CV166-SA-JAD, 2009 U.S. Dist. LEXIS 17487, *5-6 (D. Miss. Mar. 4, 2009). A violation of the federal Medicaid law does not necessarily equate to a violation of Utah state law. Thus, this case is “poles apart” from *Grable. McVeigh*, 547 U.S. at 700 (distinguishing *Grable* where the meaning of a federal statute was “the only legal or factual issue contested . . .”).

The State has not pled that violation of federal Medicaid law gives rise to any of its causes of action. The State has not pled that any of its Utah state law causes of action are dependent on the definition of the term “medically accepted.” The Court and the Defendants must accept Plaintiff’s pleading as it is; Defendants cannot raise a federal question by asserting that they will defend themselves by proving compliance with the federal Medicaid law. *Caterpillar*, 482 U.S. at 392 (stating that “it is . . . settled law that a case may *not* be removed to federal court on the basis of a federal defense”). Plaintiff’s claims neither “arise under” federal law nor implicate a federal issue that is actually in dispute. Therefore, there is no federal question jurisdiction and Plaintiff’s case must be remanded to Utah state court.

2. This matter has been decided in *Utah v. Eli Lilly & Co.*

Defendants’ attempt to distinguish this action from *Utah v. Eli Lilly & Co.*, 509 F. Supp. 2d 1016 (D. Utah 2007), is unpersuasive. Defendants claim in their Notice of Removal that Utah’s case here is in some way different than its claims in the Zyprexa litigation against Eli Lilly. Defendants are incorrect. The claims asserted by Utah against Janssen and AsrtaZeneca

are virtually identical to those asserted against Eli Lilly in the Zyprexa litigation² and this case should be remanded for the same reasons stated by Judge Stewart.

Defendants argue that Utah's complaint alleges only "federal grounds" as a basis for recovery. *See* Notice of Removal at 7. However, the State has made its claims based on "exclusively state law" and expressly disclaimed all federal causes of action. *See* Pltf. Amend. Cmplt. at 8. Just as alleged in Utah's Zyprexa case, Utah brings claims under the Utah False Claims Act, theories of product liability, fraud and negligent misrepresentation, negligence and pattern of unlawful activity under Utah Code §§ 76-10-1601 *et seq.* *Compare* Pltf. Amend. Cmplt. at 35-43 *with Eli Lilly & Co.*, 509 F. Supp. 2d at 1018. Thus, it is clear that Utah's complaint alleges only "state law grounds" and no "federal grounds" of recovery.

Next, Defendants attempt to distinguish this case from the Zyprexa litigation based on the fact that the State's claims under the Utah False Claims Act allegedly turn "*solely* on the State's rights and obligations under the Federal Medicaid statute." *See* Notice of Removal at 7. Again, this is inaccurate, and even if it were not inaccurate Judge Stewart determined that federal question jurisdiction on this basis does not exist. First, Defendants' assertion that Utah was, and continues to be, "responsible for the amounts underlying the Medicaid claims at issue, [is] a defense which raises a federal question, and such is inadequate to confer federal jurisdiction." *Eli Lilly & Co.*, 509 F. Supp. 2d at 1022 (citing *Merrell Dow Pharma., Inc. v. Thompson*, 478 U.S. 804, 808 (1986)). Second, the State's claims under the Utah False Claims Act simply adopt a federal standard. "[T]he mere presence of a federal standard embedded in a state law cause of action is not sufficient to warrant federal subject matter jurisdiction where there is no federal remedy for a violation of the federal statute." *Id.* And, finally, as Judge Stewart stated, the

² The only noticeable difference between the claims in this case and the claims in Utah's Zyprexa case is that Utah did not assert claims for breach of warranty here.

absence of a federal remedy and the potential to disturb the “congressionally approved balance of federal and state judicial responsibilities” demonstrates that removal of this case was improper because there is no basis for jurisdiction in this Court. *Id.* at 1023-25.

In the present matter, the State asserts only state law claims in the Complaint, and Defendants’ liability will depend upon their respective breach of duties created by state law. No federal law will be applied in adjudicating the foregoing claims. The State will need to prove whether the Defendants were deceptive in marketing their drugs, whether the State paid money for drugs to Medicaid recipients for uses that were not FDA-approved or supported by the designated compendia, whether the drugs were in defective condition, unreasonably dangerous for certain users, and whether there were other violations of state law.

3. Other jurisdictions have remanded similar cases, including those seeking to recover Medicaid funds.

As the Court is aware, approximately twelve years ago every Attorney General brought state law claims against the tobacco industry that necessarily involved recovery of Medicaid expenses and implicated federal tobacco labeling issues as well. Yet, every one of those cases remained in state court.

In *Philip Morris*, the United States District Court for the District of Massachusetts considered the Commonwealth’s motion to remand its causes of action seeking to recover Medicaid funds paid on behalf of Massachusetts citizens suffering from diseases caused by smoking. *Philip Morris*, 942 F. Supp. at 694. The state law based causes of action were asserted against the backdrop of Title XIX of the Social Security Act, 42 U.S.C. section 1396, *et seq.*, which is the federal legislation establishing the Medicaid program. Under Title XIX, the federal government “shares the costs of Medicaid with the States

that elect to participate in the program.” *Id.* In return, participating States are to comply with requirements imposed by the Act and by the Secretary of Health and Human Services.” *Atkins v. Rivera*, 477 U.S. 154, 156-57 (1986).

The District Court rejected defendants’ assertion of federal jurisdiction and ordered the case to be remanded to state court, stating:

vindication of the rights that Massachusetts claims under its own statutory and common law will not turn on any construction of federal law. Nor is any proposition of federal law an essential element of any of Massachusetts’ claims. *Whether the defendants, as ‘third parties’ are liable to Massachusetts for costs expended under Medicaid...will be judged by reference to Massachusetts law.*

Id. at 694 (emphasis added). Further, “though the federal statute requires a State to enforce such third party liability where it may be found, Title XIX does not establish any ground for such liability, nor does it even require that any ground for liability be established.” *Id.* The court noted that “no obligation is imposed on the State to see to it that such a legal liability does exist. And where it does exist, federal law has nothing to say about its proof, and the action to establish liability may proceed on entirely non-federal grounds.” *Id.*

The vast majority of courts considering analogous cases where states seek recovery of Medicaid funds have followed this ruling. For example, the Attorney General of New Mexico recently brought separate suits against Janssen and AstraZeneca under state statutory and common law, as the State of Utah does here, alleging that the deceptive marketing campaign for Risperdal and Seroquel resulted in the improper expenditure of state Medicaid funds. In *New Mexico v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, No. 08-CV-0779 (D. N.M. Jan. 26, 2009), the Court granted the State’s motion to remand, noting that the State’s allegations of improper expenditure of Medicaid funds “does not require a construction of the Medicaid statute or the State’s obligations under that statute. It merely requires an examination

of the facts surrounding defendant's conduct to determine whether the State's claims, brought under state law, have merit." *Slip op.* at 4. The court observed that the complaint alleged violations of state law that resulted from defendants' deception of "physicians and consumers in various ways," holding that: "the State's right to recover will not necessarily depend on resolution of a substantial question of federal law, as would be required to find federal jurisdiction over the case." *Id.* at 5.

On July 16, 2009, the same court also granted the State of New Mexico's motion to remand in *New Mexico v. AstraZeneca Pharmaceuticals, L.P.*, No. 09-CV-0390 (D. N.M. July 16, 2009). The Court reiterated that the federal regulations and statutes governing both the FDA and the Medicaid program would not come into play during the litigation of the State's claims. "Those claims are based on allegations of fraud, misrepresentation, failure to warn of Seroquel's dangers, negligence, and strict liability, among other allegations. None of the claims allege that Defendants are liable simply for promoting off-label uses of Seroquel in violation of federal law." *Slip op.* at 5.

The Court in *State of South Carolina ex rel. McMaster v. Astra Zeneca Pharmaceuticals, L.P.*, No. 09-CV-387-HFF, 2009 U.S. Dist. LEXIS 39174 (D. S.C. May 5, 2009), reached the same conclusion when considering a motion to remand in a comparable action. "Plaintiff's complaint asserts that Defendants committed Medicaid fraud by intentionally promoting non-medically necessary uses of Seroquel, which resulted in additional costs to the State through its Medicaid reimbursement to pharmacies. This claim arises under state law, and, as pled, has little, if anything to do with 'off-label' uses" *Id.* at *10-11. Further, in holding that "Defendants liability will solely depend upon their respective breach of duties as defined and created by state law," *Id.* at *13, in the related *Janssen* case, the court observed that "the central

question is whether the Defendants' advertising and promotion methods violate [South Carolina] tort law, not what is or is not a medically accepted indication or medically necessary use [under a federal standard]." *State ex rel. McMaster v. Janssen Pharmaceutica, Inc.*, No. 7:07-1452-HMH, 2007 U.S. Dist. Lexis 49904, *6 (D. S.C. July 10, 2007) (citing *Pennsylvania*, 511 F. Supp. 2d at 581-82). The Court's reasoning is directly applicable to this case. The State's reference to the term "medically necessary" in the Complaint as a component of the scope of Medicaid drug reimbursement does not present a disputed federal issue.

The overwhelming majority of courts discussing the federal role in the administration of Medicaid have also held that any federal issue raised by such a role fails the *Grable* test and is insufficient to confer federal jurisdiction. *See State v. Ortho-McNeil-Janssen Pharms., Inc.*, No. 1:08CV166-SA-JAD, 2009 U.S. Dist. LEXIS 17487 (D. Miss. Mar. 4, 2009); *State ex rel. McDaniel v. AstraZeneca Pharms., L.P.*, No. 4:08CV00601 BSM, 2008 U.S. Dist. LEXIS 67306 (E.D. Ark. Aug. 25, 2008) (remanding similar Seroquel case to state court); *State ex rel. McDaniel v. Janssen Pharmaceutica, Inc.*, No. 4:07-CV-001210-WRW, 2008 U.S. Dist. LEXIS 107769 (E.D. Ark. Mar. 25, 2008) (remanding case based on similar state claims regarding Risperdal); *State ex rel. McMaster v. Janssen Pharmaceutica, Inc.*, No. 7:07-1452-HMH, 2007 U.S. Dist. LEXIS 49904 (D. S.C. July 10, 2007); *Commonwealth v. Eli Lilly & Co.*, 511 F. Supp. 2d at 581 (remanding similar case to state court and noting "[e]ven though 'medically accepted indication' is defined by federal law, liability under the state law claims presented here nonetheless does not depend on the violation of any federal standard or statute.").³

³ *See also State v. Abbott Labs., Inc.*, 469 F. Supp. 2d 842, 852 (D. Haw. 2006) (remanding to state court claims for recovery of Medicare co-payments); *State ex rel. Nixon v. Mylan Labs., Inc.*, No. 06-CV-603 HEA, 2006 U.S. Dist. LEXIS 32570 (E.D. Mo. May 23, 2006) (remanding case seeking damages for allegedly excessive reimbursement of Medicaid funds); *State v. Abbott Labs.*, 390 F. Supp. 2d 815 (W.D. Wisc. 2005) (remanding to state court suit by state based on

4. Utah's Complaint does not implicate a sufficient federal interest to confer federal jurisdiction.

Under *Grable*, “federal jurisdiction demands not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum.” *Grable*, 545 U.S. at 313; *see also State v. Janssen Pharmaceutica, Inc.*, 2007 U.S. Dist. LEXIS 49904, at *3-4.

In assessing the substantiality, or strength, of a purported federal interest, *Grable* instructs courts to apply a two-part balancing test. First, because removal jurisdiction is statutory, courts should assess the extent to which the exercise of jurisdiction is consistent with Congressional intent. *Grable*, 545 U.S. at 317 (*citing Merrell Dow*, 478 U.S. at 810). Second, courts should consider the nature of the federal and state interests and the resulting effect the exercise of jurisdiction would have on the traditional balance of responsibilities between state and federal courts. *Id.*

a. Congress did not intend for State Medicaid recovery claims to be heard in federal courts.

Rejecting federal jurisdiction, the Court in *Merrell Dow* noted that “[t]he significance of the necessary assumption that there is no federal private cause of action...cannot be overstated.” *Id.* at 812. The Court concluded, “that the Congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a Congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently ‘substantial’ to confer federal-question jurisdiction.” *Id.* at 814.

state law claims for, *inter alia*, Medicaid fraud and false representation); *State v. Pharmacia Corp.*, No. 05-CV-1394, 2005 U.S. Dist. LEXIS 27638, (D. Minn. Oct. 24, 2005) (remanding case asserting claims for, *inter alia*, state Medicaid fraud and false advertising).

The Court in *Grable* further clarified the *Merrell Dow* opinion. In re-affirming *Merrell Dow*, the *Grable* Court warned about the very type of untoward expansion of federal jurisdiction that Defendants are attempting here:

The [*Merrell Dow*] Court saw the missing cause of action not as a missing federal door key, always required, but as a missing welcome mat, required in the circumstances, when exercising federal jurisdiction over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues. For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases.

Grable, 545 U.S. at 318. In other words, if Congress had intended such a massive shift of traditional state court cases into federal court, such intent would have been made clear.

Following *Grable* and *Merrell Dow*, two facts are relevant to this Court's inquiry regarding Congress' intent to create federal jurisdiction over the State's claims. First, there is no private right of action in the federal Medicaid statute. Second, Congress requires states to seek recovery of Medicaid funds from liable third parties. 42 U.S.C. § 1396(a)(25). Taken together, these two facts are dispositive evidence of a congressional determination that section 1331 does not encompass State Medicaid recovery actions. Congress's requirement that States recover Medicaid funds could easily have been coupled with a precise mechanism for such recovery. It was not. Without such a federal mechanism, the clear inference is that Congress intended that States accomplish recovery using state law based theories.

According to *Philip Morris*, "[n]othing in Title XIX suggests that Congress intended that state suits to recover Medicaid funds from liable third parties should be thought of as presenting federal, rather than State, claims. On the contrary, the language of the statute itself shows the congressional intent rather plainly to have been to commit the collection process to those remedies available for such purposes under state law." *Philip Morris*, 942 F. Supp. at 696. *See*

State v. Lutheran Ctr. for the Aging Inc., 957 F. Supp. 393, 403 (E.D.N.Y. 1997) (“[W]here a federal statute such as Medicaid requires a state to enforce liability against a third party but does not provide the ground for that liability, nor require establishment of a ground for liability, federal jurisdiction will not lie.”); *see also Commonwealth v. Eli Lilly & Co.*, 511 F. Supp. 2d 576, 585 (E.D. Pa. 2007) (“there is no meaningful indication that Congress intended to confer federal jurisdiction over state law causes of actions implicating the federal statutes involved here, namely, the FDCA and Title XIX of the Social Security Act”); *State v. Abbott Labs., Inc.*, 469 F. Supp. 2d 842, 856 (D. Haw. 2006) (noting that “if Congress had thought that AWP and other Medicare provisions implicated a substantial federal interest, it could have ensured that only federal courts would hear such cases. It did not.”).

This very issue was addressed by Judge Stewart in *Utah v. Eli Lilly & Co.*, 509 F. Supp. 2d 1016 (D. Utah 2007). As stated by the Court:

The *Empire* case, declining to extend *Grable*, reaffirmed the importance of a federal court’s responsibility to look for some indication that Congress intended the exercise of federal jurisdiction over claims ordinarily resolved in state courts, and specifically noted that the category established by *Grable* was slim. As the Supreme Court emphasized in *Empire*, federal courts should await a clear signal from Congress before treating such auxiliary claims as arising under the laws of the United States.

Id. at 1023.

Here, as in *Empire*, if Congress had intended that cases between States and third parties to recover Medicaid funds be heard in federal court, it could have included such a provision, but it did not, and its silence is fatal to Defendants’ argument. *See id.* (“The absence of any signal by Congress is especially important here where Congress has specifically required states to seek reimbursement from legally liable third parties, but has provided no federal cause of action to do so.”).

b. The exercise of federal jurisdiction over this case would upset the balance between state and federal courts.

The Supreme Court has held that there is a greater importance on the impact of exercising federal jurisdiction on federalism when a sovereign State brings the removed claim. *See Franchise Tax*, 463 U.S. at 22. The court noted “considerations of comity make us reluctant to snatch cases which a State has brought from the courts of that State unless some clear rule demands it.” *Id.*

Particularly, where a State seeks to vindicate its own rights by pursuing claims for the recovery of money paid previously by the State on behalf of its Medicaid participants, the balance tilts heavily in favor of State adjudication. *See, e.g., State v. AstraZeneca Pharmaceuticals, L.P.*, No. 09-CV-0390; *State ex rel. McMaster v. AstraZeneca Pharmaceuticals, L.P.*, No. 09-CV-387-HFF, 2009 U.S. Dist. LEXIS 39174 (D. S.C. May 5, 2009); *State v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, No. 08-CV-166, 2009 U.S. Dist. LEXIS 17487 (D. Miss. March 4, 2009); *State ex rel. Nixon v. Mylan Laboratories, Inc.*, No. 4:06CV603 HEA, 2006 U.S. Dist. LEXIS 32570 (E.D. Mo. May 23, 2006).

Further, “even when the state action discloses a contested and substantial federal question, the exercise of federal jurisdiction is subject to a possible veto. For the federal issue will ultimately qualify for a federal forum only if federal jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331.” *Grable*, 545 U.S. at 313; *see also State ex rel. McMaster v. Janssen Pharmaceutica, Inc.*, No. 07-CV-1452-HMH, 2007 U.S. Dist. LEXIS 49904, at *7 (D. S.C. July 10, 2007). In *Merrell Dow*, even though an essential element of the plaintiff’s cause of action turned upon the resolution of an actual and disputed question of federal law, the Supreme Court refused to find jurisdiction because doing so would invite

a large number of state law cases to be filed in or removed to federal court, thereby significantly changing the division of labor between state and federal courts. *Id.* at 813. In *Grable*, however, the Court found that the exercise of federal jurisdiction would only have a “microscopic effect” on the state-federal division of labor in the courts. *Grable*, 545 U.S. at 315.

The Constitution and the judiciary statute both contain strong indicators that civil actions involving sovereign states should proceed in state courts, and there is no federal interest in providing a federal forum merely because a state is a litigant. The Eleventh Amendment precludes any federal jurisdiction over claims against a state, when brought by citizens of another state. And, the diversity statute, 28 U.S.C. section 1332, does not encompass lawsuits brought by or against a state.

D. Defendants’ reliance on a single court in support of denial of remand is misplaced.

Defendants exclusively rely on a number of denials of remand issued by Judge Weinstein in the Zyprexa Multidistrict Litigation,⁴ which included similar claims brought against Eli Lilly related to its antipsychotic drug, Zyprexa. When considering the State of Montana’s claims against Eli Lilly, the court stated that there is “a split of authority on the matter,” noting five federal district court opinions in which the courts “remanded virtually identical cases.” *In re Zyprexa Prods. Liab. Litig.*, No. 07-CV-1933, 2008 U.S. Dist. LEXIS 10355, *11 (E.D.N.Y. Feb. 12, 2008). The only authority the court cited in which remand was denied in similar cases consisted of its own opinions in other Zyprexa cases brought by three separate

⁴ See *West Virginia ex rel. McGraw v. Eli Lilly & Co.*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007) (“*West Virginia*”); *In re Zyprexa Products Liab. Litig.*, No. 7-cv-645, 2007 U.S. Dist. LEXIS 98321 (E.D.N.Y. June 5, 2007) (“*Mississippi*”); *In re Zyprexa Products Liab. Litig.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005) (“*Louisiana*”).

States.⁵ *Id.* at *9-10. An analysis of these opinions reveals that they are without basis in precedent.

Regarding *Louisiana*, the State of Louisiana's complaint contained no federal cause of action and no allegation that liability under state law was derivative of violations of federal law. While the court mentioned *Grable*, it did not apply its two-part test. Instead, the court's opinion was based on factors that other courts have determined to be insufficient to center jurisdiction—namely, that the state sought to recover money that had, at least in part, originated in the federal system, and that the acts alleged in the petition violated the FDCA as well as state law. *See, e.g., Commonwealth v. Eli Lilly & Co.*, 511 F. Supp. at 582 (“[T]he Commonwealth’s allegation that the Defendants failed to adequately warn Medicaid . . . participants of the risks associated with their respective drugs turns not on a violation of federal labeling standards, but on a violation of Pennsylvania common law.”). If the MDL court were correct, every case involving federal government funds would be subject to jurisdiction under section 1331.

Moreover, the MDL court in *Louisiana* improperly based federal jurisdiction on the state's allegations of violations of federal law as evidence of violations of state law. But, the mere presence of a federal standard embedded in a state-law cause of action is not enough to warrant federal question jurisdiction. *Merrell Dow*, 478 U.S. at 810-17 (1986); *State v. Eli Lilly & Co.*, 509 F. Supp. 2d 1016, 1022 (D. Utah 2007).

⁵ Likewise, the United States District Courts for the Eastern District of Pennsylvania, the District of Utah, and the District of Alaska took explicit notice of the Eastern District of New York's *Louisiana* opinion in granting remand of those three States' claims against Eli Lilly. *Commonwealth v. Eli Lilly & Co.*, 511 F. Supp. 2d at 584 n. 3 (noting *West Virginia* as well); *State v. Eli Lilly & Co.*, 509 F. Supp. 2d at 1020 n. 12 (noting *Mississippi* and *West Virginia* as well); *State v. Eli Lilly & Co.*, No. 06-cv-0088, 2006 U.S. Dist. LEXIS 52783, *2 (D. Alaska July 28, 2006).

Finally, in *Louisiana* the court undertook no assessment of *Grable*'s requirement that the exercise of jurisdiction not upset federalism. Under *Grable*, "there must always be an assessment of any disruptive portent in exercising federal question." 545 U.S. at 314. No such assessment was made in deciding Louisiana's motion to remand.

In its denial of the *West Virginia* motion to remand, the court reiterated its holding denying Louisiana remand, with one addition. 476 F. Supp. 2d at 231-32. The court found that federal participation in the administration of Medicaid, plus its partial funding, created a federal question in claims involving Medicaid funds. 476 F. Supp. 2d at 233-34. Again the court was mistaken in its analysis. *See also Mississippi*, 2007 U.S. Dist. LEXIS 98321, at *2.

The Complaint here neither contains nor implicates any contested issue of federal law. Further, a complete adjudication of the claims in the Complaint will require no construction or application of federal law. Accordingly, as there is no contested federal issue and no basis for jurisdiction under section 1331, this Court should grant the State's motion to remand.

III. CONCLUSION


Under the well-pleaded complaint rule, federal jurisdiction must appear on the face of the plaintiff's complaint. Here, it is clear that Utah has alleged only violations of Utah law under Utah statutes and Utah common law. Defendants cannot establish federal jurisdiction through reliance on a federal defense.

Furthermore, as pled, Utah's Amended Complaint fails to raise or implicate a disputed, substantial question of federal law. Utah's claims do not satisfy the standard in *Grable* and its progeny.

As such, Defendants have failed to carry their burden of establishing federal subject matter jurisdiction. Plaintiff, therefore, respectfully requests the Court remand this case to the Third Judicial District Court of the State of Utah.

DATED this 26th day of June, 2010.

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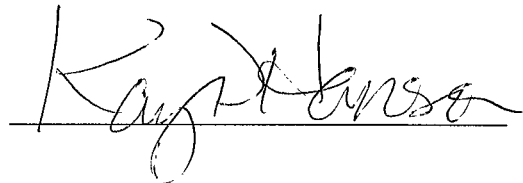
I hereby certify that on the 30 day of June, 2010 a true and correct copy of

PLAINTIFF'S MOTION TO REMAND FOR LACK OF SUBJECT MATTER

JURISDICTION was mailed by U.S. Mail, postage prepaid, to the following:

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A handwritten signature in black ink, appearing to read "Kay Hansen", is written over a horizontal line.